

Department of Energy

Germantown, MD 20874-1290

MAR 1 2 1996

Dr. Inessa Drobyshevskya Minister of Health Miasnikova St. 39 220010 Minsk Belarus

Dear Dr. Drobyshevskya:

Because of an unexpected personal matter, I will not be visiting Minsk on March 18-21, 1996. I am sorry that it precludes my visit. I was very much looking forward to meeting with you to discuss our mutual work. Dr. Elaine Gallin, the Deputy Director of my office, and Dr. Mohandas Bhat are still planning to visit Minsk and to represent our office at the "First International Conference of the European Commission, Belarus, Russian Federation and Ukraine on the Radiological Consequences of the Chernobyl Accident."

For your information, I am enclosing a revised draft of a Funding Arrangement between the U.S. Department of Energy and the Ministry of Health of Belarus. The major revision in this document (described on page 2, #3) is the total funding level for supplemental personnel support that we are able to commit to the Belarus/American Thyroid Project. We have identified additional funds from other sources and we are now able to commit a total of \$80,000 for 1 year of support. I am very pleased that \$80,000 is twice what we originally believed we could offer. Dr. Gallin and members of the American team would like to review this document with you and your staff during their upcoming visit to Minsk. It is our hope that we can finalize the Funding Arrangement during this visit.

Drs. Gallin and Bhat will be arriving in Minsk on Sunday, March 17, 1996. They both plan to attend the Chernobyl Conference during their visit, but will take time to meet with you and Dr. Krisenko whenever you are available. Dr. Gallin's only firm commitment at this time is to speak in my place at the Chernobyl Conference on Monday morning, March 18, 1996.

Thank you for your understanding and assistance.

Sincerely,

Frank Hawkins

Director

Office of International Health Programs

Enclosure

cc w/enclosure:
Nicola Krissenko, Belarus Project Director
James Taylor, NRC
Jacob Wechselberger, NRC
Shlomo Yaniv, NRC
Faye Austin, NCI
Bruce Wachholz, NCI
Carol Kessler, DOS
Europe Team, EH-63

DRAFT 8 March 1996

FUNDING ARRANGEMENT

Between the Department of Energy of the United States of America and the Ministry of Health of Belarus for Support of the United States-Belarus Thyroid Study

Purpose:

The purpose of this Funding Arrangement is to establish the framework for the receipt, distribution, and accountability of funds to be provided by the U.S. Department of Energy (hereafter referred to as the DOE) to the Ministry of Health of Belarus (hereafter referred to as the Ministry) in support of research activities carried out in accordance with the "Letter Arrangement for Continuing Cooperation on the Implementation of the Scientific Protocol for the Study of Thyroid Cancer and Other Thyroid Disease in Belarus Following The Chernobyl Accident," which was signed in Washington, D.C., on 26 May 1994. Separate arrangements are being utilized to procure equipment and supplies used in this study; the U.S. Government has already committed to the purchase of more than \$500,000 worth of equipment and supplies during the 1995–1996 years. The work/milestones to be done under this Arrangement are detailed in Annex 1. The format for financial reporting requirements is described in Annex II. The project will be referred to as the BelAm Thyroid Study.

Parties:

The responsible parties will be the Director, Office of International Health Programs of the U.S. Department of Energy, and the Deputy Minister of Health of Belarus in charge of Chernobyl Affairs, Ministry of Health, Belarus.

Scope:

The scope of the Arrangement pertains only to those funds transferred directly by the DOE to the Ministry for the purpose of support and services for activities directly related to the BelAm Thyroid Study.

¹ The U.S. agencies working together on this protocol are the DOE, the National Cancer Institute and the Nuclear Regulatory Comission.

Areas of Agreement:

- 1. The DOE will provide to the Ministry, U.S. monies to be allocated, distributed, and used solely for the development and implementation of the BelAm Thyroid Study.
- 2. With the signing of this document and concurrence on the milestones in Annex I for the first 3 months, the first transfer of U.S. monies will be initiated in the amount of \$20,000.
- 3. The U.S. will contribute a total of \$20,000 every 3 months for a 1-year time period (total U.S. contribution = \$80,000) to supplement personnel costs incurred on work related to the BelAm Thyroid studies. Both parties agree that the following objectives should be accomplished:
 - o The Government of Belarus will provide salary support for personnel working on the study upon signing of this agreement;
 - o An exemption will be provided from all custom fees and taxes on all equipment, vehicles and other material provided by the U.S. for use in this project within a month of signing this agreement; and
 - o The BelAm Thyroid Study will be accorded the status of a State Project as soon as possible and no later than 3 months after signing this agreement.
- 4. U.S. monies will be allocated in the following manner:
 - o No more than 10 percent of the total of all DOE monies shall be used for administrative or indirect costs directly related to the BelAm Thyroid Study; and
 - o The remainder of the monies shall be allocated for supplementary personnel support. Personnel support is understood to include primarily direct salary supplementation allocated to individual project personnel based on the percent effort each spends on the BelAm Thyroid Study and their professional duties in the study. Funds will be allocated in two categories: support personnel will be paid a minimum of \$50 per month with a maximum five-fold increase depending upon the level of responsibility; professional staff will be paid a minimum of \$100 per month with a maximum five-fold increase depending on the position of responsibility.
- 5. U.S. monies will be transferred directly to the Ministry of Health, Belarus. They should not be subject to taxes, duties, or other handling or administrative charges beyond modest bank transfer fees.

- 6. Subsequent funding will be transferred on a quarterly basis provided that the DOE is in receipt of:
 - o An appropriate expenditure report for the previous funding period using the format specified in Annex II;
 - o The milestones accomplished in the previous funding period as specified in Annex I;
 - o Updated milestones covering the next funding period; and
 - o An invoice from the Ministry describing the individuals to be supported for the next funding period and the tasks that each individual will be working on.
- 7. Reports are to be sent to the DOE Office of International Health Programs with copies sent to the National Cancer Institute.
- 8. Continuation of incremental funding is contingent upon the Government of Belarus providing salary support for the BelAm Thyroid Study.

Oversight:

At intervals not to exceed every 6 months, U.S. representatives will visit the Ministry to review the administration of the BelAm Thyroid Study and the accounting for the expenditure of U.S. funds. The Ministry will provide office space and necessary information and assistance to the U.S. representative while in Minsk.

General Provisions:

Cooperation under this Agreement will be in accordance with the laws and regulations under which each party operates. Monies shall be provided subject to the availability of appropriated funds and to the mutual consent of the two parties.

Entry into Force and Terminations:

This Funding Agreement shall enter into force upon signing by both parties and remain in force for 1 year. This Agreement may be amended at any time by mutual consent of the parties. This Agreement may be terminated by either party upon 90 days written notice to the other party.

For the U.S. Department of Energy Office of Health Studies	For the Ministry of Health of Belarus	
•		
Date:	Date:	

BelAm THYROID STUDY

Tasks and Milestones

The BelAm Study will consist of a number of tasks. Some of these tasks may begin or be completed at different times, while others, such as the clinical examination of the cohort and dose estimation, are expected to continue for many years. As the Study progresses, some tasks may be re-defined and others added.

Milestones can be associated with those tasks. On completion of each milestone, a report will be prepared and submitted to DOE.

The tasks, as currently identified, are given below along with the milestones expected to be accomplished within 3 months of signing the Funding Arrangement. Milestones expected to be accomplished at later dates during the first year of the BelAm Thyroid Study will be identified within 1 month of signing the Funding Arrangement.

Task No. 1: The management and administration of the BelAm Thyroid Study.

Milestone 1: Approval of the BelAm Thyroid Study as a State Project.

Milestone 2: Organizational structure of the BelAm Thyroid Study and identification

of persons responsible for each Task.

Milestone 3: Selection of the Members of the Oversight Committee and proposed

date for the first meeting of that Committee.

Task No. 2. The establishment of the cohort of subject for study.

Milestone 4: Designation of 600 potential subject meeting quality criteria for the

Study cohort.

Milestone 5: Location of 200 subject accessible to the Minsk Dispensary.

Task No. 3: The invitation and scheduling of subject for endocrinologic examination.

Milestone 6: Preparation of the letters of invitation, software, and procedures for

inviting and scheduling subject for examination.

Task No. 4: The endocrinologic examination of subjects, including subsequent diagnostic procedures leading to the establishment of the final pathologic diagnosis.

Milestone 7: Completion of all pilot work on the screening program, including the

laboratory work.

Milestone 8: Completion of all training and certification in Minsk Dispensary.

- Milestone 9: Completion of installation and testing of equipment to store thyroid images in the magnetic-optical drives in Minsk Dispensary.
- Milestone 10: Revision of the Operations Manual and study forms based on the pilot work.
- Task No. 5: The establishment and operation of a central laboratory.
 - Milestone 11: Completion of preparations for storage of blood and microscopic slides.
- Task No. 6: The establishment and operation of a Data Coordinating Center for data management.
 - Milestone 12: Transfer of DCC from Masherova Str. to the new place (if it is necessary) and reinstallation of all equipment.
 - Milestone 13: Design of software for printing BAR-CODE labels and registration logs.
 - Milestone 14: Creation of the filing systems for hard-copy (paper) records in all divisions of the project.
- Task No. 7: The estimation of individual thyroid doses for members of the cohort.
 - Milestone 15: Compilation of data on the response of the SRP-68 detector for sources of various energies located in the thyroid and in other parts of the body.
 - Milestone 16: Feasibility of deriving Iodine-131 fallout from Iodine-129 measurements in soil: results of the campaign of soil sampling of May 1993.

Quarterly Report Format for U.S.-Belarus Thyroid Study

		Reporting Period	t:
Institution:			
Address:			
Name of Contact Person:		Telephone #:	Fax #:
Reporting Items		· ·	
A. Project Personnel Support	Person-Months*	Task	
			Amount in U.S. \$\$
Please indicate each person recei	ving		\$\$
support	·	· · · · · · · · · · · · · · · · · · ·	\$\$
			\$\$
			\$\$
			\$\$
*Number of months worked by each person		Subtotat>	ss
			•
B. Adminstrative/Indirect Costs			Amount in U.S. \$5
•			\$\$
		. I.	\$\$
·			\$\$
			SS
		Subtotal>	 \$\$
Please explain costs			
	;	Total Costs	100

Annex 1

Belam THYROID STUDY

Tasks and milestones

The BelAm Study will consist of a number of tasks. Some of these tasks may begin or be completed at different times, while others, such as the clinical examination of the cohort and dose estimation, are expected to continue for many years. As the Study progresses, some tasks may be re-defined and others added.

Milestones can be associated with those tasks. On completion of each milestone, a report will be prepared and submitted to DOE.

The tasks, as currently identified, are given below along with the milestones expected to be accomplished by the end of April, 1996. Milestones expected to be accomplished at later dates during the first year of the BelAm Thyroid Study will be identified by the end of March, 1996.

- Task No. 1: The management and administration of the BelAm Thyroid Study.
 - Milestone 1: Approval of the BelAm Thyroid Study as a State Project.
 - Milestone 2: Organizational structure of the BelAm Thyroid Study and identification of persons responsible for each Task.
 - Milestone 3: Selection of the Members of the Oversight Committee and proposed date for the first meeting of that Committee.
- Task No. 2: The establishment of the cohort of subjects for study.
 - Milestone 4: Designation of 600 potential subjects meeting quality criteria for the Study cohort.
 - Milestone 5: Location of 200 subjects accessible to the Minsk Dispensary.
- Task No. 3: The invitation and scheduling of subjects for endocrinologic examination.
 - Milestone 6: Preparation of the letters of invitation, software, and procedures for inviting and scheduling subjects for examination.
- Task No. 4: The endocrinologic examination of subjects, including subsequent diagnostic procedures leading to the establishment of the final pathologic diagnosis.
 - Milestone 7: Completion of all pilot work on the screening program, including the laboratory work.
 - Milestone 8: Completion of all training and certification in Minsk Dispensary
 - Milestone 9: Completion of installation and testing of equipment to store thyroid images in the magnetic-optical drives in Minsk Dispensary
 - Milestone: 10.Rev**ision of the Operations Manual and study forms** based on the pilot work

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- Task No. 5: The establishment and operation of a central laboratory.
 - Milestone 11:Completion of preparations for storage of blood and microscopic slides.
- Task No. 6: The establishment and operation of a Data Coordinating Center for data management.
 - Milestone 12 ?: Transfer of DCC from Masherova Str. to the new place (if it is necessary) and reinstallation of all equipment
 - Milestone 13:Design of software for printing BAR-CODE labels and registration logs.
 - Milestone 14:Creation of the filing systems for hard-copy (paper) records in all divisions of the project.
- Task No. 7: The estimation of individual thyroid doses for members of the cohort.
 - Milestone 15:Compilation of data on the response of the SRP-68 detector for sources of various energies located in the thyroid and in other parts of the body.
 - Milestone 16: Feasibility of deriving lodine-131 fallout from lodine-129 measurements in soil: results of the campaign of soil sampling of May 1993.